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LACOURCIERE, K	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/199,129	BYRUM ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 4-12, drawn to a nucleic acid encoding a soybean protein, classified in class 536, subclass 23.1.

II. Claim 2, drawn to a soybean protein, classified in class 530, subclass 350.

III. Claims 13-17, drawn to a method of determining a mutation in a plant, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different products. For example, the nucleic acids of Group I are composed of nucleotides, which is materially different than the polypeptides of Group II, which are composed of amino acids.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the nucleic acids of Group I can be used in a materially different method, for example, to express a polypeptide in a method of purification.

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Group II are not used in the method of Group III and the polypeptides of Group II function as a peptide, which is different than the methods of Group III, which function to identify a mutation in a plant.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. ***Sequence Election Requirement Applicable to All Groups***

In addition, Groups I-III detailed above read on patentably distinct complex sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For each of Groups I-III, the Applicants must further elect a **single** sequence for examination.. (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical

compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

It has been decided that, due to the high burden placed on the Office to search sequences, Applicant is required to elect **ONE** independent and distinct sequence. Examination will be restricted to only the **ONE** elected sequence.

7. During a telephone conversation with Linda Parker on 03-09-01 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 4-12 and further elected these claims for SEQ ID NO:1. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2, 3 and 13-17 and sequences 2-5521 are withdrawn from

further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Specification

9. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see for example page 6). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1 and 4-12 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Claims 1 and 4-12 are drawn to a nucleic acid encoding a soybean protein or fragments of a soybean protein. SEQ ID NO:1 is an EST isolated from soybean leaf tissue. Applicant asserts a general utility for this EST (as well as 5520 other EST isolated from the same source) as useful in the isolation of agronomically important genes, as well as generic uses such as antibody production, gene expression probe, marker, etc. The application does not disclose a utility specific for a nucleic acid comprising SEQ ID NO:1 or a specific utility or activity for a protein or fragment encoded by a nucleic acid encoding SEQ ID NO:1, nor does it disclose a specific utility for any full length gene which could be isolated using SEQ ID NO:1.

The claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed uses of the nucleic acids (and proteins encoded by said nucleic acids) are not specific and are generally applicable to any nucleic acid and/or protein. The specification states that the nucleic acid compounds may be useful as probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages. Similarly, protein may be used for detection of expression, antibody production, Western blots, etc. These are non-specific

uses that are applicable to nucleic acids and/or proteins in general and not particular or specific to the nucleic acids (and proteins encoded by said nucleic acids) being claimed.

Further, the claimed nucleic acid (and proteins encoded by said nucleic acids) are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have specific and substantial utilities. The research contemplated by applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid compounds (or

proteins encoded by said nucleic acid compounds) such that another non-asserted utility would be well established for the compounds.

Because there is no specific utility for a nucleic acid comprising SEQ ID NO:1 (as discussed above), there is also no specific utility for a plant comprising a nucleic acid comprising SEQ ID NO:1, or its complement, nor is there any specific utility for methods of determining the level or pattern of a protein which has no specific utility using SEQ ID NO:1 or its complement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1 and 4-12 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

12. Claims 1 and 4-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO: 1. SEQ ID NO: 1 meets the written description provisions of 35 USC 112, first paragraph. However, SEQ ID NO:1 is a partial sequence, and the proper open reading frame has not been disclosed. Claims 1 and 4-12 are directed to encompass full length gene sequences (ie. gene sequences yet to be discovered) and cDNAs comprising SEQ ID NO:1, sequences that hybridize to SEQ ID NO: 1, and so forth, as well as plants comprising said sequences and methods which utilize said sequences. None of these sequences meet the written description provision of 35 USC 112, first paragraph. For example, cDNA comprising a partial sequence encompasses a wide variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region, however, the specification does not disclose an open reading frame for SEQ ID NO:1 and, therefore, would not be representative of the genus of cDNA's because no information regarding the coding capacity of any cDNA molecule would be disclosed. In the instant case, the specification discloses only a single common structural feature shared by the claimed genus, ie. SEQ ID NO:1, and this disclosed structural feature does not constitute a substantial portion of the claimed genus. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its

claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-

Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1 and 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4-12 are indefinite because they are drawn to compositions and methods which include SEQ ID NO:2-5521. SEQ ID NO:2-5521 and methods which utilize SEQ ID NO:2-5521 are non-elected subject matter and, therefore, claims 1 and 4-12 are considered to be indefinite. Claims 1 and 4-12 have only been considered to the extent that they read on the elected subject matter, SEQ ID NO:1.

Claim 1 is indefinite due to the recitation "fragment thereof". One skilled in the art would not know the metes and bounds of the claimed nucleic acid molecules because the scope of the phrase "fragment" is unclear as to what size polypeptide constitutes a "fragment" of a soybean protein. Therefore, one skilled in the art would not know what nucleic acid molecules are encompassed by this claim.

Claims 4 and 5 (and dependent claims) are indefinite due to the recitation "structural nucleic acid molecule". It is unclear how a nucleic acid molecule is "structural", for example, does the nucleic acid molecule provide a structural element to the claimed plant or encode a polypeptide which is a structural element of the claimed plant? Due to the indefinite nature of the term "structural nucleic acid molecule" the metes and bounds of this term can not be determined and, therefore, one skilled in the art would not know what plants are encompassed by these claims. For the purposes of the examination of the instant case, the word "structural" is not being considered.

Claim 8 (and dependent claims) are indefinite due to the recitation "said enzyme" in the 13th line of the claim. There is no antecedent basis for this term in the claim.

Claim 8 (and dependent claims) are further indefinite due to the recitation "said plant cell or plant tissue", throughout the claim (lines 9-10, 12, 16). There is antecedent basis for the term "said plant cell", however. the antecedent basis for the term "plant tissue" (which also appears to be modified by the word "said") is not clear. This rejection would be obviated by amending the claim to insert the phrase "or plant tissue" after the phrase "a plant cell" in the first line of the claim.

Claim 8 (and dependent claims) are further indefinite due to the recitation "predictive" in the last line of the claim. The claimed method is not meant to "predict" the level or pattern of a protein (which implies future levels or patterns of a protein), but to determine the present level or pattern of a protein. It is suggested that the conclusion of claim 8 be amended to reflect the

outcome set forth in the preamble, for example, by replacing the word "predictive" with the word "indicative" in the last line of the claim.

Conclusion

Any inquiry concerning this communication should be directed to Karen A. Lacourciere at telephone number (703)308-7523.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
March 22, 2001

SEAN McGARRY
PRIMARY EXAMINER
TC 1600